JUL 2 0 2000

K001087

510(k) Summary

Submitted By: Karen Bradburn
Regulatory Affairs Coordinator
COOK INCORPORATED
925 South Curry Pike
P.O. Box 489
Bloomington, IN 47402

Device:
Trade Name: None
Proposed Classification Name: Catheter, Cardiovascular Balloon Type (79LIT)

Predicate Devices

The PTA balloon catheter is similar in terms of intended use, materials of construction and technological characteristics to predicate devices reviewed as devices for dilation of lesions in peripheral arteries (iliac, renal popliteal, infra popliteal, femoral and ilio femoral).

Device Description

The PTA Balloon Catheter is a double lumen catheter with a balloon near the distal tip. The catheter features a minimally compliant balloon constructed from high density polyethylene material. The balloon is designed to expand to a specified diameter and length at a specific pressure as labeled. The balloon catheter is provided in an overall length of 135cm. The catheter will be made in four balloon diameters of 2.5mm, 3.0mm, 3.5mm and 4.0mm. Balloon lengths will be 1.5cm, 2.0cm, 3.0cm and 4.5cm. The catheter is compatible with 0.018-inch standard PTA wire guides. Two radiopaque marker bands located at the proximal and distal ends of the balloon segment to facilitate fluoroscopic visualization of the balloon during use.

Substantial Equivalence

The PTA Balloon Catheter is similar to many devices already in commercial distribution for percutaneous transluminal angioplasty (PTA). The similar indications for use and technological characteristics of the PTA Balloon Catheter as compared to the predicate devices supports a determination of substantial equivalency. Other companies with similar balloon catheters for PTA are Medi-Tech Corporation of Watertown, Massachusetts, United States Catheter and Instrument of C.R. Bard, as well as COOK INCORPORATED.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Ms. Karen Bradburn
Regulatory Affairs Coordinator
COOK Incorporated
925 South Curry Pike
Bloomington, IN 47402

Re: K001087
Trade Name: PTA Balloon Catheter
Regulatory Class: II (two)
Product Code: LIT
Dated: July 7, 2000
Received: July 10, 2000

Dear Ms. Bradburn:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4586. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

COOK INCORPORATED
Response to Request for Additional Information
D.C.#K001087, PTA Balloon Catheter

510(k) Number (if known): K001087

Device Name: PTA Balloon Catheter

Indications for Use:

For percutaneous transluminal angioplasty of lesions in peripheral arteries including iliac, renal, popliteal, infrapopliteal, femoral and ilio femoral and is also intended to treat obstructive lesions of native or synthetic arteriovenous dialysis fistulae.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-the-Counter Use_____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices

510(k) Number K001087